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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION: Sun et al

Serial No. 09/682,440 Art Unit:3732

Filed: September 4, 2001 Examiner:T. Manahan

For: WAX-LIKE POLYMERIZABLE DENTAL MATERIAL, MEHTOD AND SHAPED PRODUCT

The Commissioner of Patents and Trademarks
Washington, D.C. 20231

DECLARATION UNDER 37 CFR 1.132

Declarant Benjamin J. Sun declares that:

I am an inventor in the above captioned patent application.

I received a PhD in Chemistry from the University of Southern California in 1994.

I have been employed by Dentsply International Inc. since 1998.

My current title is Senior Research Scientist.

DENTSPLY Research & Development Corp., the assignee of the above captioned patent application, is a wholly owned subsidiary of Dentsply International Inc.

I am familiar with:

Tateosian et al US patent 4711913,
Antonucci et al US patent 5037473,
Volkel et al US patent 6057383 and

Moszner et al, Die Angewandte Makromolekulare Chemie 245 (1997) 155-164.

"Wax-like" as used in the above captioned patent application (see page 1) refers to material which becomes dimensionally stable (is nonfluid) at 23°C.

Under my direction and control the procedure of Example 1 of Antonucci et al US patent 5037473 was followed to form a very viscous (dough-like or paste-like) material.

Under my direction and control the procedure of Example 2 of Tateosian et al US patent 4711913 was followed to form a very viscous (dough-like or paste-like) material.

Under my direction and control the procedure of Examples 5 and 7 of the above captioned patent application was followed to form wax-like polymerizable material.

Under my direction and control the very viscous material of Example 1 of Antonucci et al US patent 5037473, the very viscous material of Example 2 of Tateosian et al US patent 4711913 and the wax-like polymerizable material Example 7 of the above captioned patent application were tested according to ADA (American Dental Association) consistency test specification 19, paragraph 4.3.4, JAVA Vol 94, April, 1977, pages 734-737 (see EXHIBIT A). The test results are listed in Table 1, and show that at 23°C the very viscous materials of Antonucci et al and Tateosian et al are not dimensionally stable. They are fluids (see Hawley's Condensed Chemical Dictionary 1997, page 507, fluid: EXHIBIT B), as they change shape uniformly in response to external force imposed on them. Under the test procedures the diameter of the very viscous material of Antonucci et al uniformly increased 60.1 percent, the diameter of the very vsicous material of Tateosian et al uniformly increased 58.0 percent, while the diameter of the wax-like polymerizable material of the above captioned patent application did not change.

The test results show that at 23°C the materials of Tateosian et al, and Antonucci et al, are not dimensionally stable, and are fluid.

The materials of Tateosian et al, and Antonucci et al are not wax-like, as referred to in the above captioned patent application, because at 23°C they are not dimensionally stable, and because at 23°C they are fluid.

Table 1 shows a comparison before polymerization of the materials of Example 2 of U.S. Patent 4,711,913, Example 1 of U.S. Patent 5,037,473 and Example 7 of the above captioned patent application at 23°C.

Table 1

	material of Example 1 of 5,037,473	material of Example 2 of 4,711,913	material of Example 7 of the above captioned patent application
Diameter change according to ADA Specification 19 at 23°C	60.1% (increase)	58.0% (increase)	0.0% (no change)
Dimensionally stable at 23°C.	NO	NO	YES
Fluid at 23°C	YES	YES	NO
Changes shape uniformly in response to external force imposed at 23°C.	YES	YES	NO

Under my direction and control the procedure of Example 7B of Volkel et al U.S. patent 6057383 was followed to form polymerizable material, the procedure of pages 157 and 163 for the composition of Table 5 (37.3% comonomer) of Moszner et al was followed to form polymerizable material, and the procedure of Example 7 of the above captioned patent application was followed to form polymerizable wax-like material, and these polymerizable materials were polymerized and tested according to ASTM test D790 1997, pages 145-152 EXHIBIT C) for flexural strength (psi), and flexural modulus (kpsi). Table 2 shows a comparison after polymerization of the materials of Example 7B of Volkel et al, U.S. patent 6,057,383, and Example 7 of the above captioned patent application.

Table 2

	Flexural strength (psi)	Flexural Modulus (kpsi)
U.S. Patent 6,057,383 (Volkel et al) Example 7B	2897	207.9
Example 7 of the above captioned patent application	16820	446.5
Moszner et al, pages 162 and 163 for the composition of Table 5 (37.3% comonomer)	1977	

A high strength dental polymeric material, as used in the above captioned patent application, has a flexural modulus of at least 250,000 psi and a flexural strength of at least 5,000 psi (see page 2 of the above captioned patent application). The polymerized products of Volkel et al and Moszner et al do not have a flexural modulus of at least 250,000 psi and a flexural strength of at least 5,000 psi. Thus, the polymerized product of Volkel et al and Moszner et al are not a high strength dental polymeric material, as referred to in the above captioned patent application.

The polymerized product of in the above captioned patent application is superior by having a flexural strength which is more than 500 percent greater, than the flexural strength of the polymerized product of Volkel et al. The polymerized product of in the above captioned patent application is superior by having a flexural modulus which is more than twice as great as the flexural modulus of the polymerized product of Volkel et al.

The polymerized product of Volkel et al does not have the minimum strength required for making dentures. The polymerized products of Volkel et al and Moszner et al are more than 60 percent below the minimum flexural strength required for making dentures, and the flexural modulus of Volkel et al is insufficient for making dentures, as shown in Table 3, (see International Standard ISO 1567, 1999E Dentistry- denture base polymers, pages 1-6: EXHIBIT D).

Table 3

	Flexural strength	Flexural Modulus
Lowest strength requirements for denture base polymers: ISO 1567, 1999e	60 Mpa [8700 psi]	1500 MPa [217,500 psi]
US Patent 6,057,383 (Volkel et al) Example 7B	2897 psi	207,900 psi
Percent from sufficient strength (%) of Volkel et al	- 66.6 %	-4.4%
The above captioned patent application (Example 5)	16,820 psi	446,500 psi
Percent from sufficient strength (%) of the above captioned patent application	193.3 %	205.3 %
Moszner et al, Table 5 (37.3% comonomer)	1977 psi	
Percent from sufficient strength (%) of Moszner et al	-87.3 %	

The polymerized product of the above captioned patent application has much more than the minimum strength required for making dentures. The polymerized product of the above captioned patent application has 193.3 percent of the minimum flexural strength required for making dentures, and its flexural modulus is more than twice the amount needed to be sufficient for making dentures, as shown in Table 3, (see International Standard ISO 1567, 1999E Dentistry- denture base polymers, pages 1-6; EXHIBIT D).

Further Declarant saith not.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 11-7-02

Benjamin J. Sun